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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,124	12/27/2005	Stanley R Terlecky	TERLECKY1A	5930

1444 7590 08/29/2008

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
08/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,124	TERLECKY ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,29,34-36,41,42,45-53 and 56-59* is/are pending in the application.

4a) Of the above claim(s) *13-19,22-28,34,36,42,45-53,56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,20,21,35,41,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 27, 28, 30-33, 37-40, 43, 44, 54, and 55 have been canceled. Claims 1-26, 29, 34-36, 41, 42, 45-53, 56, 57 and new claims 58-59 are at issue and are present for examination.

Applicant's election with traverse of Group I, claims 1-12, 20, 21, and 35 (and now including claim 41 and new claims 58 and 59 in the reply filed on 4/18/08 is acknowledged. The traversal is on the ground(s) that the modified catalase as is now claimed (i.e., human catalase in which SEQ ID NO:1 is replaced with a PTS1 sequence). This is not found persuasive because this is clearly not a "special technical feature" shared by all groups as it is not in fact even a feature of all groups as groups II and V do not require this modified catalase. Furthermore, even for the remaining groups this is not a special technical feature as it does not define an feature which constitute a contribution over the art as shown by the art rejections of claim 1 herein. Applicants further suggest that amendments to claims 41 and 42 put them within the scope of the elected groups. While the examiner agrees that claim 41 is within the scope of the elected group the amendment of claim 42 to a method for reducing the concentration of hydrogen peroxide in a cell *in vivo*, is in effect a method of treating a subject and thus this claim recites the subject matter of group VIII and is included therein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-19, 22-28, 34, 36, 42, 45-53, 56 and 57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/18/08.

Claim 58 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since claim 12 now recites replacing SEQ ID NO:1 with the SKL sequence and the sequence immediately preceding SEQ ID NO:1 in human catalase is AARE, the claim modified catalase could not have KANL immediately preceding the SKL.

Claims 2-11, 21 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (upon which claims 3-11 and 21 depend) is confusing in the recitation of "further comprising, to the amino-terminal

side of Xaa_3, n additional amino acid residues wherein n is an integer between 1 and about 17" because human catalase is 527 amino acids in length and thus any modified human catalase in which SEQ ID NO:1 (i.e., the C-terminal 4 amino acids) has been replaced with a PTS comprising a sequence $Xaa_3Xaa_2Xaa_1$ will necessarily have at least 523 amino acids amino terminal to Xaa_3. Furthermore, claims 7 and 8 are particularly confusing as the residues immediately preceding SEQ ID NO:1 in human catalase that will be residues Xaa_6 and Xaa_5 are R and E respectively such that it is unclear how they can be a hydrophobic amino acid or Leu, Val, Ile, Ala or Gly.

Claim 59 is confusing in the recitation of "primer being represented by SEQ ID NO:18" as it is unclear if this is the same as "primer of SEQ ID NO:18" or if it is meant to include something else. For purposes of further examination it is assumed to be identical to "primer of SEQ ID NO:18".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9-12, 35, 41, 58, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheik et al. in view of Trelease et al.

Sheikh et al. teach a human catalase variant in which a SKL peptide was added to the carboxy terminal leucine residue of the human catalase sequence. Sheikh et al. further teach the introduction of the variant catalase protein into cells and show the reduction of oxidation of several peroxisomal proteins and teach that this is likely due to the reduction of hydrogen peroxide levels in the peroxisomes of cells in which the variant catalase was present in the peroxisomes. Sheik et al did not remove the naturally occurring human KANL peroxisome targeting peptide but instead added the consensus PTS1 sequence i.e., SKL to the carboxy-terminus of the natural human KANL peroxisome targeting peptide.

Trelease et al. teach a rat liver catalase variant in which the carboxy terminal KANL peptide was replaced with an KSHL tripeptide. Trelease et al. further teach the introduction of

the variant catalase protein into the peroxisomes of cells where it will reduce the hydrogen peroxide levels in the peroxisomes of the cells in which the variant catalase was present and that a carboxy-terminal SKL peptide is also a known peroxisome targeting signal.

In view of the disclosure of Trelease et al. an ordinary skilled artisan would have understood that an alternative means of modifying the human catalase protein to a protein with a consensus PTS1 sequence i.e., SKL, as taught by Sheik et al. would be the replacement of the non-consensus KANL peptide with the consensus PTS1 peptide i.e., KSHL or KSKL and would have found it obvious to make a modified human catalase in which the KANL is replaced as claimed.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheik et al. in view of Trelease et al. as applied to claims 1-6, 9-12, 35, 41, 58, and 59 above, and further in view of Fujiwara et al.

Sheikh et al. and Trelease et al. are discussed above.

Fuijiwara et al. teach that lack of proper transport of catalase to the peroxisomes of cells of patients with some peroxisome biogenesis disorders is linked to the inability of the mutant transport machinery of these patients to efficiently transport the non-standard PTS1 sequence of mammalian catalases

even though the mutant transport machinery of these patients is capable of transporting sufficient amounts of other peroxisomal proteins having a typical PTS1 sequence. Fuijiwara clearly suggest that even for normal mammalian cells the KANL PTS of catalase is not as efficiently recognized by the peroxisome transport proteins as are typical PTS sequences.

Therefore, it would have been obvious make a pharmaceutical composition of the modified human catalase as made obvious by the disclosure of Sheikh et al. and Trelease et al. in order to treat a patient with peroxisome biogenesis disorders linked to the inability of the peroxisome transport machinery to efficiently transport the non-standard PTS1 sequence with modified human catalase which include the full catalase catalytic domain but include a typical PTS1 sequence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652